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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : C12M 1/30, A61B 10/00, B01L 3/00 — A1

(11) International Publication Number: WO 97/23596

(43) International Publication Date: 3 July 1997 (03.07.97)

(21) International Application Number: PCT/GB96/03166

(22) International Filing Date: 19 December 1996 (19.12.96)

(30) Priority Data:
9526204.4 21 December 1995 (21.12.95) GB

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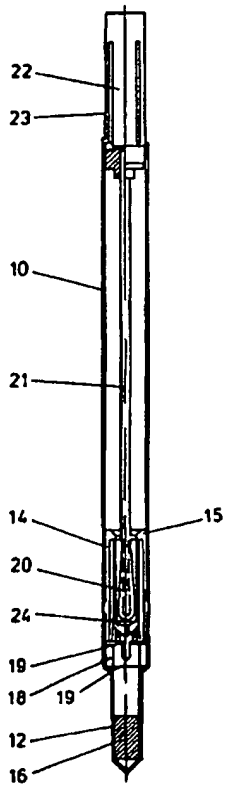
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: SAMPLING AND ASSAY DEVICE

(57) Abstract

A sampling and assay device comprises a tubular enclosure (10) which is provided adjacent one end with one or more transverse barriers (19) to form separate compartments for respective chemical components. The device further comprises a sample swab (20) at least partially disposed within a cap-shaped shuttle (24). The swab is arranged to be moved longitudinally of the tubular enclosure to correspondingly displace the shuttle (24) and rupture the barrier or barriers (19) in order to mix the chemical components.



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Sampling and assay device

This invention relates to a single-shot sampling and assay device, particularly but not solely for carrying out a hygiene test using ATP-bioluminescence.

Many biological and chemical assay procedures require a number of substances to be combined so as to effect some chemical or physical reaction. For example, a test for a substance X may rely on its ability to react with a substance Y so as to produce a substance Z, where substance Z may have a suitable indicative characteristic such as its colour.

In certain circumstances, such a test may be complicated by associated factors, for example, the chemical instability of one or more of the test reagents, and therefore require additional stages to be included in the procedure.

For example, in hygiene tests based upon the ATP-bioluminescence reaction, a number of precise quantities of reagent are typically required to be combined, and therefore the testing procedures tend to be very laborious and error prone. An example of such a test is that for Adenosine 5'-Triphosphate (ATP) using the enzyme Firefly Luciferase. Being a chemical component common to all living cells, ATP is found in very low concentrations in foodstuffs due partly to the presence of micro-organisms. The level of ATP in a specimen may therefore be used as an indicator of general hygiene conditions. Bioluminescence testing enables the quantity of ATP in a sample to be accurately determined by measuring the degree of luminescent reaction between the sample and a critical quantity of Firefly Luciferase, using a photometer or luminometer.

A variety of procedures and devices have been suggested for carrying out such tests, in which precise quantities of the required chemical reagents, in either liquid or lyophilised form, are segregated within the body of an assay device, so as to be combined upon the introduction of a specimen, typically carried upon a swab.

It is known for such devices to comprise foil seals or barriers in order to isolate the reagents from one another.

However, the majority of these devices are unsatisfactory due to the inherent complexities of their construction and due to inefficiencies of the various means provided for rupturing the seals and for combining the exposed reagents.

We have now devised a device which overcomes the limitations of existing assay devices and provides a more easily manufactured and more efficient mechanism by which the segregated testing reagents are released and combined.

In accordance with the present invention, there is provided a sampling and assay device, comprising a tubular enclosure provided adjacent one end thereof with one or more transverse barriers to form separate compartments for respective chemical components, and a swab having its head at least partially disposed within a cap-shaped shuttle, the swab being arranged for movement longitudinally of said tubular enclosure to correspondingly displace the shuttle and rupture said barrier or barriers in order to mix said chemical components.

Preferably said barrier, or each of said barriers, comprises a foil membrane.

Preferably the swab includes a stem attached to a plug or stopper which is, initially, partially inserted into an open end of the tubular enclosure. Depression of the plug or stopper, to cause it to become fully inserted, displaces the swab and the shuttle, thereby rupturing the barrier or barriers. Thus, in use, the swab is removed, used to take a sample (typically by wiping over a surface to be tested) and is then re-inserted into the tubular enclosure for transit before subsequently being fully depressed. Preferably the plug or stopper forms part of a handle which includes a latching finger which requires lateral depression before the swab can be displaced longitudinally to rupture the barrier or barriers.

Preferably the shuttle comprises one or more projections or fins on its leading end, arranged to rupture the barrier or barriers with a minimum force and encouraging them to tear in a regular manner.

Preferably the shuttle is formed as a light interference fit within the tubular enclosure and its leading end is formed with one or more apertures, to effect an

efficient mixing of the chemical components forced through said apertures and onto the swab. This action may be arranged to provide a brake against the depression of the swab and shuttle to ensure adequate time for dissolution of the reagents.

Preferably a pair of the barriers form the opposing walls of a container or reagent pot, which is secured within the tubular enclosure.

Preferably the tubular enclosure comprises a main body part and a cap-shaped end member closing one end of the main body part. Preferably the reagent pot is inserted into the cap-shaped end member and then this end member, containing another of the chemical components, is fitted and sealed onto the end of the main body part: more particularly, the cap-shaped end member and main body part may be fitted onto opposite ends of a tubular collar, which gives rigidity to the construction.

It is typically required for the head of the swab to be pre-moistened: the tubular enclosure is sealed to prevent evaporation from the swab head during the period between manufacture and use of the device. However, some evaporation can occur through the wall of the enclosure. We have now devised an arrangement for preventing this.

Thus, also in accordance with this invention, there is provided a sampling and assay device, comprising a tubular enclosure, a pre-moistened swab disposed within said tubular enclosure, and a metal foil wrapped around and adhered to the outer surface of said tubular enclosure.

It will be appreciated that the metal foil (typically aluminium foil) acts as an impermeable barrier to moisture and so prevents loss of moisture from the swab.

Preferably the metal foil is laminated to a pre-printed or otherwise marked paper or polymer outer surface layer, to form an identifying label for the device. Preferably the metal foil is provided with areas on which the user may write additional information, e.g. the date and/or place at which a sample is taken.

An embodiment of the present invention will now be described by way of example only and with reference to the accompanying drawings, in which:

FIGURE 1 is a longitudinal section through a combined sampling and assay device in accordance with the present invention, the device being shown prior to use; and

FIGURES 2 to 4 are views, on a larger scale, of alternative profiles for the end of the shuttle of the device.

Referring to Figure 1 of the drawings, there is shown a combined sample and assay device which comprises a tubular enclosure formed from a main body part 10 and a cap-shaped end member 12 fitted over opposite ends of a tubular collar 14. The end member or cuvette 12 contains a volume of liquid 16 and is sealed by a reagent pot 18 before being fitted onto the collar 14. The reagent pot 18 comprises a ring-shaped housing which is sealed across its opposite ends by metal foil membranes 19: the reagent pot 18 contains a lyophilised reagent. The device further comprises a swab having an absorbent head 20 carried on a stem 21, the swab being inserted into the main body 10 and held in place by a plug part of a handle 22, attached to the opposite end of the swab stem 21, being partially inserted into the upper end of the main body 10. The swab head 20 is located within a cap-shaped shuttle 24, which has one or more apertures formed through its leading, conical-shaped end. Preferably there is a small clearance between the swab and the internal surface of the shuttle 24 to optimise, in use of the device, the flow and mixing of reagents with the sample on the swab head 20. The shuttle 24 is positioned within the collar 14 and is temporarily held in that position, preferably by being a sprung interference fit within the collar 14: a rim 15 around the top of the collar 14 prevents the shuttle 24 being withdrawn when, in use, the swab is withdrawn from the device. However, although the shuttle is shown in Figure 1 as extending to the top of the collar 14, instead it may be substantially shorter and enclose only a lower end portion of the swab head 20.

In its manufactured condition as shown in Figure 1, the swab head 20 is pre-moistened with a swab solution and a tamper-evident seal (not shown) is formed over the handle 22 and the upper end of the main body part 10. In use, the latter seal is broken, the swab is removed and its head 20 is wiped over a surface to be tested, then the swab is inserted again

into the tubular enclosure. At this stage, the swab may be stored or transported before activating the reagents of the device. When an operator wishes to initiate the reaction (e.g. after transporting the device to a luminometer), the swab is now fully depressed within the tubular enclosure 10, 12.

In order to depress the swab into its tubular enclosure, it is necessary first to depress laterally a latching finger 23 of the handle 22, the finger 23 otherwise abutting the end of the body part 10. Then in depressing the swab, the shuttle 24 is displaced longitudinally of the device, causing the shuttle 24 to rupture the membranes 19 of the reagent pot 18. All or most of the lyophilised contents of the reagent pot 18 are thereby forced out into the liquid 16. The shuttle 24 is further displaced into the cap-shaped end member 12 of the device, in which it is a close sliding fit. The re-hydrated reagent, resulting from the mixture of the lyophilised contents of the pot 18 with the liquid 16, is forced up through the apertures in the end of the shuttle 24 and into contact with the swab head 20. The liquid may also be forced through the swab head, thus increasing contact between the reagent and the sample on the swab head.

Use of the shuttle 24 improves the membrane-piercing action, as compared with use of the swab head alone. Also the shuttle promotes an increased mixing of the lyophilised reagent from the pot 18 and the liquid 16 in the cuvette 12. In addition, the arrangement may be such that sufficient back-pressure is generated by the restricted flow of re-hydrated reagent through the shuttle apertures, that the speed of depression of the shuttle is limited, and the shuttle enters the liquid 16 in the cuvette 12 at a uniform rate, thus optimising the mixing process. If the reagents are sensitive to shear, preferably the user pauses before completing the depressing action. A further advantage of the use of the shuttle is that it prevents direct contact between the pre-moistened swab and the reagent in the pot 18: this direct contact is undesirable in the case of certain reagents.

In the case of an ATP-bioluminescence test, the material in the reagent pot 18 comprises an enzyme, typically firefly luciferase, and the liquid 16 in the cuvette 12

comprises an appropriate diluent. After the swab has been depressed to enable the chemical components to mix and pass to the swab head 20 for any reaction with its sample to occur, the device is inserted into a luminometer to detect and measure any light output. For this purpose, the shuttle 24 and the cuvette 12 are transparent.

It is important for the membranes 19 of the reagent pot 18 to rupture in a controlled manner, so that after rupture they do not obscure the side wall of the device, through which any light emission is to be observed. The end of the shuttle 24 may have a simple conical shape, as shown in Figure 2. Preferably however, the end of the shuttle 24 is provided with a series of radiating fins 26, as shown in Figure 3 or 4. These fins reduce the force required to puncture the membranes 19, which in turn allows the use of longer and/or more flexible swabs without unacceptable buckling. The fins 26 also prevent contact between the leading end of the shuttle 24 and the bottom of the cuvette 12 (which might trap solid reagent). The fins 26 further ensure that the membranes 19 tear in a regular manner, with minimal risk of obscuring the side wall of the device. Moreover, the fins 26 ensure that the lower membrane of the reagent pot 18 is ruptured without compacting the lyophilised reagent in the pot (which would undesirably increase the dissolution time).

As previously mentioned, in the device as manufactured, the swab head 20 is pre-moistened. Although the swab is contained within a sealed enclosure, some of the moisture can evaporate through the wall of the main body part 10 of the device. In order to prevent this, an aluminium foil (not shown) is adhered around the outside of the body part 10 of the device: this foil extends the full length of the body part 10 and around its full circumference and may overlap the joint to the collar 14 and/or cap 12 to improve security against loss and improve the moisture barrier. The foil is printed or otherwise marked to form an identifying label of the device, and is preferably formed with areas on which the user may write further information, e.g. the date and place at which the sample is taken. The foil thus avoids the need to package the device in a sachet or the like. A further advantage of the

foil is that it enables the device to be detected automatically, e.g. should it inadvertently fall into a food production line.

Claims

1) A sampling and assay device, comprising a tubular enclosure provided adjacent one end thereof with one or more transverse barriers to form separate compartments for respective chemical components, and a swab having its head at least partially disposed within a cap-shaped shuttle, the swab being arranged for movement longitudinally of said tubular enclosure to correspondingly displace the shuttle and rupture said barrier or barriers in order to mix said chemical components.

2) A device as claimed in claim 1, in which the or each said barrier comprises a foil membrane.

3) A device as claimed in claim 1 or 2, comprising a container disposed within said tubular enclosure, and comprising a pair of said barriers which form opposite walls of said container.

4) A device as claimed in any preceding claim, in which said tubular enclosure comprises a main body part and a cap-shaped end member closing one end of said main body part.

5) A device as claimed in claim 4, in which said main body part and cap-shaped end member are fitted to opposite ends of a tubular collar.

6) A device as claimed in any preceding claim, in which said shuttle seats as a light interference fit within said tubular enclosure.

7) A device as claimed in any preceding claim, in which said shuttle is formed at its leading end with one or more apertures or through-passages.

8) A device as claimed in any preceding claim, in which said shuttle is formed at its leading end with at least one projection.

9) A device as claimed in claim 8, in which the or each said projection comprises a fin.

10) A device as claimed in any preceding claim, in which said swab includes a stem attached to a plug or stopper which fits into an open end of said tubular enclosure.

11) A device as claimed in claim 10, in which said plug or stopper includes a latch which requires lateral depression to enable said swab to be displaced sufficiently, longitudinally of said tubular enclosure, to cause said shuttle to rupture said barrier or barriers.

12) A device as claimed in any preceding claim, in which said swab is pre-moistened.

13) A device as claimed in any preceding claim, further comprising a metal foil wrapped around and adhered to the outer surface of said tubular enclosure.

14) A sampling and assay device, comprising a tubular enclosure, a pre-moistened swab disposed within said tubular enclosure, and a metal foil wrapped around and adhered to the outer surface of said tubular enclosure.

15) A device as claimed in claim 14, in which said metal foil is laminated to an outer surface layer which is marked, or able to be marked, with written or printed information

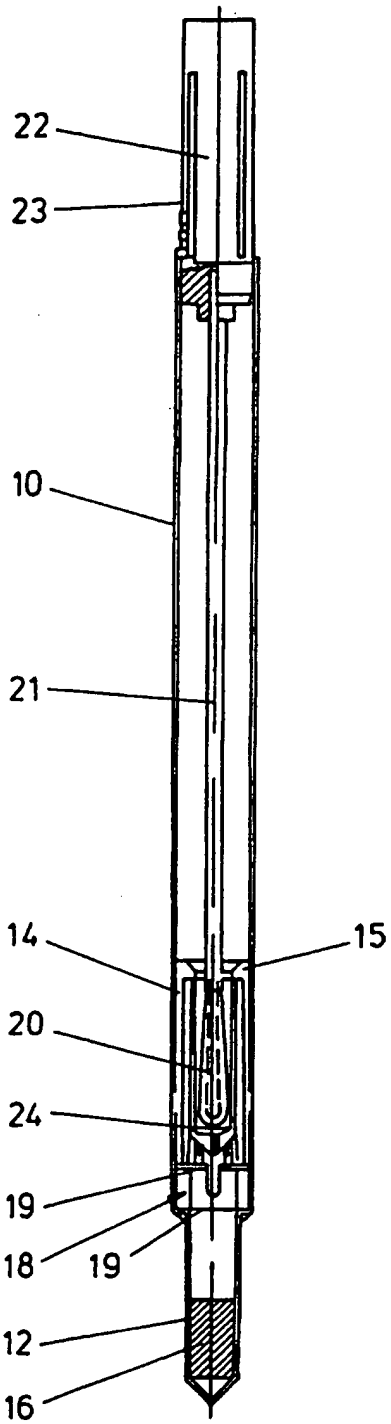

FIG. 1

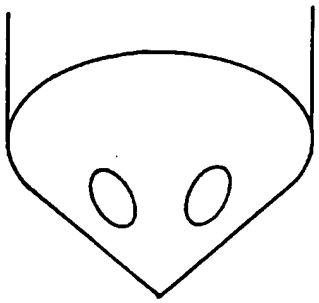

FIG. 2

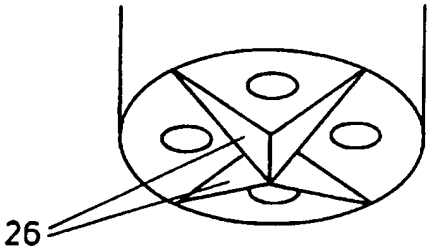

FIG. 3

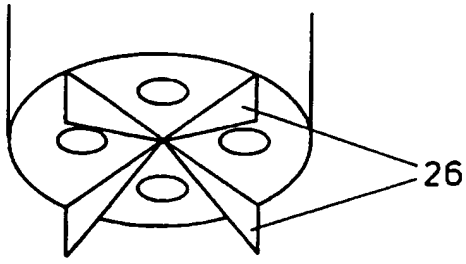

FIG. 4

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/GB 96/03166

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 C12M1/30 A61B10/00 B01L3/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 B01L C12M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95 25948 A (CELSIS INTERNATIONAL PLC ;FOOTE NICHOLAS PETER MARTIN (GB); GRANT) 28 September 1995 see page 2, line 35 - page 3, line 30	1-5,7,8, 10
X	see page 4, line 1 - line 5	7
Y	see page 4, line 6 - line 13 see page 6, line 23 - page 7, line 21; figure 4	12

Y	WO 95 07457 A (BIOTRACE LIMITED ;JOHNSON IAN ROY (GB); GOODFIELD CLIVE (GB)) 16 March 1995	14,15
Y	see page 1, line 35 - page 2, line 13 see page 5, line 7 - line 34; figure 5	12

Y	GB 1 161 528 A (PREBBLES) 13 August 1969 see page 1, column 1, line 15 - line 28	14,15

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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X	US 4 353 868 A (JOSLIN JOEL A ET AL) 12 October 1982 see column 2, line 4 - line 27; figure 1 see column 3, line 5 - line 11; figure 1 see column 3, line 33 - line 35; figures 1,3 -----	1,6,8

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte onal Application No
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